

**REMARKS**

Claims 49-91 are pending in the application.

**Election/Restriction**

The Examiner has required restriction of the invention under 35 U.S.C. § 121 to one of the following groups:

I. Claims 49-89, drawn to a method of diagnosing Hepatitis C virus, comprising contacting an isolated amino acid sequence encoded by an HCV nucleic acid molecule SEQ ID NO: 1 with a biological sample from a subject, classified in class 435, subclass 339.

II. Claims 90 and 91, drawn to a kit for diagnosing HCV, comprising an amino acid sequence immobilized on a surface and a labeled secondary anti-human antibody, classified in class 530, subclass 300.

If Group I is elected, the Examiner has further required restriction of the present invention under 35 U.S.C. § 121 to one of the following amino acid sequences which will be used in the method of detection of the presence of the antibody in the sample:

- a) SEQ ID NO: 2
- b) SEQ ID NO: 3
- c) SEQ ID NO: 4
- d) SEQ ID NO: 5
- e) SEQ ID NO: 6
- f) SEQ ID NO: 9

The Examiner is of the opinion that the inventions are distinct, each from the other because

the product as claimed can be used in a materially different process of using that product. For example the amino acid sequence can be used for immunization purposes. A search for peptide sequences is not co-extensive with a search for a method of use of the diagnostic kit comprising the peptides. It is an undue burden for the examiner to search

more than one invention. Therefore restriction for examination purposes is proper.

Furthermore, the six amino acid sequences are different structurally and must be searched not only in commercial amino acid sequence databases, but also in textual databases of non-patent literature. Searching all amino acid sequences together would present a serious search burden on the Office.

In order to be considered responsive to the instant Office Action, Applicants' hereby elect Group I (claims 49-89) directed to a method of diagnosing Hepatitis C virus, comprising contacting an isolated amino acid sequence encoded by an HCV nucleic acid molecule SEQ ID NO: 1 with a biological sample from a subject, without traverse. Applicants further elect SEQ ID NO:4, *with traverse*. Applicants traverse the restriction requirement for the following reasons.

Applicants respectfully submit that the instant Restriction Requirement is improper for the following reasons. Applicants have presented an allowable generic claim, claim 49 which embraces the use of HCV alternate reading frame polypeptides, regardless of SEQ ID NO., in methods of diagnosing HCV infection by detecting antibodies to HCV. Claim 49 is drawn to a method of diagnosing Hepatitis C virus (HCV) infection, comprising contacting an isolated, purified, or synthetic polypeptide comprising an amino acid sequence of at least 8 amino acids in length which amino acid sequence is encoded by an HCV nucleic acid molecule comprising a nucleotide sequence corresponding to SEQ ID NO:1 and translated in a reading frame corresponding to the reading frame of SEQ ID NO:1 and +1 to the standard HCV reading frame with a biological sample from a subject, under conditions where the polypeptide and an antibody that binds to the polypeptide present in the sample can bind, and determining the presence or absence of the antibody, wherein presence of the antibody indicates infection with HCV.

It is Applicants' position that given the presence of claim 49, which embraces SEQ ID Nos: 2-9, a restriction under 35 U.S.C. §121 is improper. Applicants submit that while a species election may be proper for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable, an election under 35 U.S.C. §121 is improper since the claims are linked by an allowable generic linking claim. If a species election is required, Applicants further provisionally elect SEQ ID NO:4 for search purposes only. It is Applicant's

understanding that under 35 U.S.C. §121, an election of a single species for prosecution on the merits is required, to which the claims will be restricted if no generic claim is finally held allowable. Applicants submit that at least claim 49 is generic. Applicant further understands that upon allowance of a generic claim, he will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141 *et seq.*

Moreover, Applicants submit that the examination of SEQ ID NOs: 2, 3, 4, 5, 6, and 9 in the present application would not place an undue burden on the Examiner, since the prior art searches for these sequences would be co-extensive. Specifically, Applicants point out that each of the sequences 2, 3, 4, 5, 6, and 9 encode an HCV alternate reading frame polypeptide or a fragment thereof. In addition, SEQ ID NOs:3, 4, 5, and 6 are all contained within SEQ ID NO:2 and SEQ ID NOs:5 and 6 are specific sequences related to the degenerate sequences of SEQ ID NOs:3 and 4. Furthermore, SEQ ID NO:2 and SEQ ID NO: 9 share approximately 77 percent amino acid identity. As stated in the M.P.E.P., a reasonable number of nucleotide sequences are permitted to be claimed in a single application. In particular, the M.P.E.P. states:

*[n]ormally ten sequences constitute a reasonable number for examination purposes...[a]ccordingly, in most cases, up to ten independent and distinct nucleotide sequences will be examined in a single application without restriction....*

M.P.E.P. § 803.04 . . .

Moreover, the M.P.E.P. continues:

*[i]n addition to the specifically selected sequences, those sequences which are patentably indistinct from the selected sequences will also be examined...nucleotide sequences encoding the same protein are not considered to be independent and distinct inventions and will continue to be examined together.*

M.P.E.P. § 803.04 . . .

Thus a search of the sequences encompassed by the pending claims, which encode the alternate reading frame polypeptides or fragments thereof as noted above, is a reasonable number for examination purposes and would not place a serious burden on the Examiner.

Applicants further note that the sequences of SEQ ID NOs: 2, 3, 4, 5, 6, and 9 all belong to the same search class (530) and the same subclass (350).

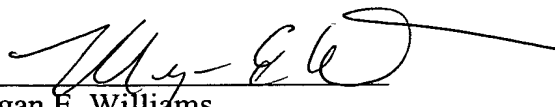
In view of the foregoing, Applicants request the Examiner to reconsider and withdraw the restriction requirement to the extent that all sequences encompassed by the pending claims be grouped together in the present application.

**CONCLUSION**

If a telephone conversation with Applicants' Attorney would expedite the prosecution of the above-identified application, the Examiner is urged to call Applicants' Attorney at (617) 227-7400.

Dated: June 26, 2006

Respectfully submitted,

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